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September 29, 1999

10/5/49

The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Betaine has been shown to be an effective lipotrophic agent.*
- (2) Lipotrophic agents promote the transportation and use of fats, helping to prevent the accumulation of fat in the liver.*
- (3) Vitamin A has an important and specific effect on lipid metabolism.*
- (4) Vitamin F complex has been shown to be important in the metabolism of blood fats.*

These statements are made for a dietary supplement containing a proprietary blend of carrot (root), dried beet (leaf) juice, beet (root), oat flour, calcium lactate, defatted wheat (germ), magnesium citrate, bovine prostate, nutritional yeast, bovine liver, bovine kidney, alfalfa flour, bovine orchic extract, bovine liver fat extract, flaxseed oil extract, mixed tocopherols, and soy bean lecithin. Other ingredients include honey, arabic gum, calcium stearate, vitamin A palmitate, gelatin, prolamine iodine (zein), ascorbic acid, and pyridoxal-5-phosphate. And the name of the product is A-F Betafood®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

) M. Holden

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